



## General

## Guideline Title

Major trauma: assessment and initial management.

# Bibliographic Source(s)

National Clinical Guideline Centre. Major trauma: assessment and initial management. London (UK): National Institute for Health and Care Excellence (NICE); 2016 Feb 17. 22 p. (NICE guideline; no. 39).

## Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

# Regulatory Alert

# FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

March 22, 2016 – Opioid pain medicines
 : The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

# Recommendations

# Major Recommendations

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Clinical Guideline Centre (NCGC) on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

The wording used in the recommendations in this guideline (for example, words such as 'offer' and 'consider') denotes the certainty with which the

recommendation is made (the strength of the recommendation) and is defined at the end of the "Major Recommendations" field.

NICE has developed four related clinical guidelines and one service delivery guideline related to the management of people with traumatic injuries including this guideline on major trauma assessment and initial management and the following guidelines:

- Fractures (complex): assessment and management
- Fractures (non-complex): assessment and management
- Major trauma: service delivery
- · Spinal injury: assessment and initial management

Recommendations below apply to both children (under 16s) and adults (16 or over) unless otherwise specified.

#### Immediate Destination after Injury

Be aware that the optimal destination for patients with major trauma is usually a major trauma centre. In some locations or circumstances intermediate care in a trauma unit might be needed for urgent treatment, in line with agreed practice within the regional trauma network.

## Airway Management in Pre-hospital and Hospital Settings

The NGC summary of the NICE guideline Major trauma: service delivery contains a recommendation for ambulance and hospital trust boards, medical directors and senior managers on drug-assisted rapid sequence induction of anaesthesia and intubation.

Use drug-assisted rapid sequence induction (RSI) of anaesthesia and intubation as the definitive method of securing the airway in patients with major trauma who cannot maintain their airway and/or ventilation.

If RSI fails, use basic airway manoeuvres and adjuncts and/or a supraglottic device until a surgical airway or assisted tracheal placement is performed.

Airway Management in Pre-hospital Settings

Aim to perform RSI as soon as possible and within 45 minutes of the initial call to the emergency services, preferably at the scene of the incident.

If RSI cannot be performed at the scene:

- Consider using a supraglottic device if the patient's airway reflexes are absent.
- Use basic airway manoeuvres and adjuncts if the patient's airway reflexes are present or supraglottic device placement is not possible.
- Transport the patient to a major trauma centre for RSI provided the journey time is 60 minutes or less.
- Only divert to a trauma unit for RSI before onward transfer if a patent airway cannot be maintained or the journey time to a major trauma centre is more than 60 minutes.

## Management of Chest Trauma in Pre-hospital Settings

Use clinical assessment to diagnose pneumothorax for the purpose of triage or intervention.

Consider using eFAST (extended focused assessment with sonography for trauma) to augment clinical assessment only if a specialist team equipped with ultrasound is immediately available and onward transfer will not be delayed.

Be aware that a negative eFAST of the chest does not exclude a pneumothorax.

Only perform chest decompression in a patient with suspected tension pneumothorax if there is haemodynamic instability or severe respiratory compromise.

Use open thoracostomy instead of needle decompression if the expertise is available, followed by a chest drain via the thoracostomy in patients who are breathing spontaneously.

Observe patients after chest decompression for signs of recurrence of the tension pneumothorax.

In patients with an open pneumothorax:

- Cover the open pneumothorax with a simple occlusive dressing and
- Observe for the development of a tension pneumothorax

#### Management of Chest Trauma in Hospital Settings

Chest Decompression of Tension Pneumothorax

In patients with tension pneumothorax, perform chest decompression before imaging only if they have either haemodynamic instability or severe respiratory compromise.

Perform chest decompression using open thoracostomy followed by a chest drain in patients with tension pneumothorax.

Imaging to Assess Chest Trauma

Imaging for chest trauma in patients with suspected chest trauma should be performed urgently, and the images should be interpreted immediately by a healthcare professional with training and skills in this area.

Consider immediate chest X-ray and/or eFAST as part of the primary survey to assess chest trauma in adults (16 or over) with severe respiratory compromise.

Consider immediate computed tomography (CT) for adults (16 or over) with suspected chest trauma without severe respiratory compromise who are responding to resuscitation or whose haemodynamic status is normal (see also recommendation below on whole-body CT).

Consider chest X-ray and/or ultrasound for first-line imaging to assess chest trauma in children (under 16s).

Do not routinely use CT for first-line imaging to assess chest trauma in children (under 16s).

Management of Haemorrhage in Pre-hospital and Hospital Settings

Dressings and Tourniquets in Pre-hospital and Hospital Settings

Use simple dressings with direct pressure to control external haemorrhage.

In patients with major limb trauma use a tourniquet if direct pressure has failed to control life-threatening haemorrhage.

Pelvic Binders in Pre-hospital Settings

If active bleeding is suspected from a pelvic fracture after blunt high-energy trauma:

- Apply a purpose-made pelvic binder or
- Consider an improvised pelvic binder, but only if a purpose-made binder does not fit

Haemostatic Agents in Pre-hospital and Hospital Settings

Use intravenous tranexamic acid<sup>1</sup> as soon as possible in patients with major trauma and active or suspected active bleeding.

Do not use intravenous tranexamic acid<sup>1</sup> more than 3 hours after injury in patients with major trauma unless there is evidence of hyperfibrinolysis.

<sup>1</sup>At the time of publication (February 2016), tranexamic acid did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

Anticoagulant Reversal in Hospital Settings

Rapidly reverse anticoagulation in patients who have major trauma with haemorrhage.

Hospital trusts that admit patients with major trauma should have a protocol for the rapid identification of patients who are taking anticoagulants and the reversal of anticoagulation agents.

Use prothrombin complex concentrate immediately in adults (16 or over) with major trauma who have active bleeding and need emergency reversal of a vitamin K antagonist.

Do not use plasma to reverse a vitamin K antagonist in patients with major trauma.

Consult a haematologist immediately for advice on adults (16 or over) who have active bleeding and need reversal of any anticoagulant agent other than a vitamin K antagonist.

Consult a haematologist immediately for advice on children (under 16s) with major trauma who have active bleeding and may need reversal of any anticoagulant agent.

Do not reverse anticoagulation in patients who do not have active or suspected bleeding.

Activating Major Haemorrhage Protocols in Hospital Settings

Use physiological criteria that include the patient's haemodynamic status and their response to immediate volume resuscitation to activate the major haemorrhage protocol.

Do not rely on a haemorrhagic risk tool applied at a single time point to determine the need for major haemorrhage protocol activation.

Circulatory Access in Pre-hospital Settings

For circulatory access in patients with major trauma in pre-hospital settings:

- Use peripheral intravenous access or
- If peripheral intravenous access fails, consider intra-osseous access

For circulatory access in children (under 16s) with major trauma, consider intra-osseous access as first-line access if peripheral access is anticipated to be difficult.

Circulatory Access in Hospital Settings

For circulatory access in patients with major trauma in hospital settings:

- Use peripheral intravenous access or
- If peripheral intravenous access fails, consider intra-osseous access while central access is being achieved

Volume Resuscitation in Pre-hospital and Hospital Settings

For patients with active bleeding use a restrictive approach to volume resuscitation until definitive early control of bleeding has been achieved.

In pre-hospital settings, titrate volume resuscitation to maintain a palpable central pulse (carotid or femoral).

In hospital settings, move rapidly to haemorrhage control, titrating volume resuscitation to maintain central circulation until control is achieved.

For patients who have haemorrhagic shock and a traumatic brain injury:

- If haemorrhagic shock is the dominant condition, continue restrictive volume resuscitation or
- If traumatic brain injury is the dominant condition, use a less restrictive volume resuscitation approach to maintain cerebral perfusion

Fluid Replacement in Pre-hospital and Hospital Settings

In pre-hospital settings only use crystalloids to replace fluid volume in patients with active bleeding if blood components are not available.

In hospital settings do not use crystalloids for patients with active bleeding. See the section on resuscitation in the NGC summary of the NICE guideline Intravenous fluid therapy in adults in hospital and the section on fluid resuscitation in the NGC summary of the NICE guideline Intravenous fluid therapy in children and young people in hospital for advice on tetrastarches.

For adults (16 or over) use a ratio of 1 unit of plasma to 1 unit of red blood cells to replace fluid volume.

For children (under 16s) use a ratio of 1 part plasma to 1 part red blood cells, and base the volume on the child's weight.

Haemorrhage Protocols in Hospital Settings

Hospital trusts should have specific major haemorrhage protocols for adults (16 or over) and children (under 16s).

For patients with active bleeding, start with a fixed-ratio protocol for blood components and change to a protocol guided by laboratory coagulation results at the earliest opportunity.

Haemorrhage Imaging in Hospital Settings

Imaging for haemorrhage in patients with suspected haemorrhage should be performed urgently, and the images should be interpreted immediately

by a healthcare professional with training and skills in this area.

Limit diagnostic imaging (such as chest and pelvis X-rays or FAST [focused assessment with sonography for trauma]) to the minimum needed to direct intervention in patients with suspected haemorrhage and haemodynamic instability who are not responding to volume resuscitation.

Be aware that a negative FAST does not exclude intraperitoneal or retroperitoneal haemorrhage.

Consider immediate CT for patients with suspected haemorrhage if they are responding to resuscitation or if their haemodynamic status is normal.

Do not use FAST or other diagnostic imaging before immediate CT in patients with major trauma.

Do not use FAST as a screening modality to determine the need for CT in patients with major trauma.

Whole-Body CT of Multiple Injuries

Use whole-body CT (consisting of a vertex-to-toes scanogram followed by a CT from vertex to mid-thigh) in adults (16 or over) with blunt major trauma and suspected multiple injuries. Patients should not be repositioned during whole-body CT.

Use clinical findings and the scanogram to direct CT of the limbs in adults (16 or over) with limb trauma.

Do not routinely use whole-body CT to image children (under 16s). Use clinical judgement to limit CT to the body areas where assessment is needed.

Damage Control Surgery

Use damage control surgery in patients with haemodynamic instability who are not responding to volume resuscitation.

Consider definitive surgery in patients with haemodynamic instability who are responding to volume resuscitation.

Use definitive surgery in patients whose haemodynamic status is normal.

Interventional Radiology

The NGC summary NICE guideline Major trauma: service delivery contains a recommendation for ambulance and hospital trust boards, medical directors and senior managers on interventional radiology and definitive open surgery.

Use interventional radiology techniques in patients with active arterial pelvic haemorrhage unless immediate open surgery is needed to control bleeding from other injuries.

Consider interventional radiology techniques in patients with solid-organ (spleen, liver or kidney) arterial haemorrhage.

Consider a joint interventional radiology and surgery strategy for arterial haemorrhage that extends to surgically inaccessible regions.

Use an endovascular stent graft in patients with blunt thoracic aortic injury.

Reducing Heat Loss in Pre-hospital and Hospital Settings

Minimise ongoing heat loss in patients with major trauma.

Pain Management in Pre-hospital and Hospital Settings

Pain Assessment

See the NICE guideline on patient experience in adult NHS services for advice on assessing pain in adults.

Assess pain regularly in patients with major trauma using a pain assessment scale suitable for the patient's age, developmental stage and cognitive function.

Continue to assess pain in hospital using the same pain assessment scale that was used in the pre-hospital setting.

Pain Relief

For patients with major trauma, use intravenous morphine as the first-line analgesic and adjust the dose as needed to achieve adequate pain relief.

If intravenous access has not been established, consider the intranasal route for atomised delivery of diamorphine or ketamine<sup>2</sup>.

Consider ketamine in analgesic doses as a second-line agent.

<sup>2</sup> At the time of publication (February 2016), neither intranasal diamorphine nor intranasal ketamine had a UK marketing authorisation for this		
indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be		
obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines	for	
further information		

## Documentation in Pre-hospital and Hospital Settings

The NGC summary of the NICE guideline Major trauma: service delivery contains recommendations for ambulance and hospital trust boards, senior managers and commissioners on documentation within a trauma network.

Recording Information in Pre-hospital Settings

Record the following in patients with major trauma in pre-hospital settings:

- Catastrophic haemorrhage
- Airway with in line spinal immobilisation
- Breathing
- Circulation
- Disability (neurological)
- · Exposure and environment

If possible, record information on whether the assessments show that the patient's condition is improving or deteriorating.

Record pre-alert information using a structured system and include all of the following:

- The patient's age and sex
- Time of incident
- Mechanism of injury
- · Injuries suspected
- Signs, including vital signs and Glasgow Coma Scale
- Treatment so far
- Estimated time of arrival at emergency department
- Special requirements
- The ambulance call sign, name of the person taking the call and time of call

## Receiving Information in Hospital Settings

A senior nurse or trauma team leader in the emergency department should receive the pre-alert information and determine the level of trauma team response according to agreed and written local guidelines.

The trauma team leader should be easily identifiable to receive the handover and the trauma team ready to receive the information.

The pre-hospital documentation, including the recorded pre-alert information, should be quickly available to the trauma team and placed in the patient's hospital notes.

Recording Information in Hospital Settings

Record the items listed in the first recommendation under "Recording Information in Pre-hospital Settings" above, as a minimum, for the primary survey.

One member of the trauma team should be designated to record all trauma team findings and interventions as they occur (take 'contemporaneous notes').

The trauma team leader should be responsible for checking the information recorded to ensure that it is complete.

Sharing Information in Hospital Settings

Follow a structured process when handing over care within the emergency department (including shift changes) and to other departments. Ensure that the handover is documented.

Ensure that all patient documentation, including images and reports, goes with patients when they are transferred to other departments or centres.

Produce a written summary, which gives the diagnosis, management plan and expected outcome, and:

- Is aimed at and sent to the patient's general practitioner (GP) within 24 hours of admission
- Includes a summary written in plain English that is understandable by patients, family members and carers
- Is readily available in the patient's records

#### Information and Support for Patients, Family Members and Carers

The NGC summary of the NICE guideline Major trauma: service delivery contains recommendations for ambulance and hospital trust boards, senior managers and commissioners on information and support for patients, family members and carer.

#### **Providing Support**

When communicating with patients, family members and carers:

- Manage expectations and avoid misinformation
- Answer questions and provide information honestly, within the limits of your knowledge
- Do not speculate and avoid being overly optimistic or pessimistic when discussing information on further investigations, diagnosis or prognosis
- · Ask if there are any other questions

The trauma team structure should include a clear point of contact for providing information to patients, family members and carers.

If possible, ask the patient if they want someone (a family member, carer or friend) with them

If the patient agrees, invite their family member, carer or friend into the resuscitation room. Ensure that they are accompanied by a member of staff and their presence does not affect assessment, diagnosis or treatment.

Support for Children and Vulnerable Adults

Allocate a dedicated member of staff to contact the next of kin and provide support for unaccompanied children and vulnerable adults.

Contact the mental health team as soon as possible for patients who have a preexisting psychological or psychiatric condition that might have contributed to their injury, or a mental health problem that might affect their wellbeing or care in hospital.

For a child or vulnerable adult with major trauma, enable their family members or carers to remain within eyesight if appropriate.

Work with family members and carers of children and vulnerable adults to provide information and support. Take into account the age, developmental stage and cognitive function of the child or vulnerable adult.

Include siblings of an injured child when offering support to family members and carers.

Providing Information

Explain to patients, family members and carers what is happening and why it is happening. Provide:

- Information on known injuries
- Details of immediate investigations and treatment, and if possible include time schedules
- Information about expected outcomes of treatment, including time to returning to usual activities and the likelihood of permanent effects on quality of life, such as pain, loss of function or psychological effects

Provide information at each stage of management (including the results of imaging) in face-to-face consultations.

Document all key communications with patients, family members and carers about the management plan.

Providing Information about Transfer from an Emergency Department

For patients who are being transferred from an emergency department to another centre, provide verbal and written information that includes:

- The reason for the transfer
- The location of the receiving centre and the patient's destination within the receiving centre

- The name and contact details of the person responsible for the patient's care at the receiving centre
- The name and contact details of the person who was responsible for the patient's care at the initial hospital

## Training and Skills

Recommendations for Ambulance and Hospital Trust Boards, Medical Directors and Senior Managers within Trauma Networks

Ensure that each healthcare professional within the trauma service has the training and skills to deliver, safely and effectively, the interventions they are required to give, in line with this guideline and the NGC summaries of the NICE guidelines Fractures (non-complex): assessment and management, Fractures (complex): assessment and management, and Spinal injury: assessment and initial management.

Enable each healthcare professional who delivers care to patients with trauma to have up-to-date training in the interventions they are required to give.

Provide education and training courses for healthcare professionals who deliver care to children with major trauma that include the following components:

- Safeguarding
- Taking into account the radiation risk of CT to children when discussing imaging for them
- The importance of the major trauma team, the roles of team members and the team leader, and working effectively in a major trauma team
- · Managing the distress families and carers may experience and breaking bad news
- The importance of clinical audit and case review

#### Definitions

Strength of Recommendations

Some recommendations can be made with more certainty than others. The Guideline Committee makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the Guideline Committee is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

Interventions That Must (or Must Not) Be Used

The Guideline Committee usually uses 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally the Guideline Committee uses 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

Interventions That Should (or Should Not) Be Used – a 'Strong' Recommendation

The Guideline Committee uses 'offer' (and similar words such as 'refer' or 'advise') when confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. The Guideline Committee uses similar forms of words (for example, 'Do not offer...') when confident that an intervention will not be of benefit for most patients.

Interventions That Could Be Used

The Guideline Committee uses 'consider' when confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

# Clinical Algorithm(s)

A National Institute for Health and Care Excellence (NICE) pathway titled "Trauma overview" is provided on the NICE Web site

# Scope

# Disease/Condition(s)

Major trauma, defined as an injury or a combination of injuries that are life-threatening and could be life changing because it may result in long-term disability

Guideline Category
Diagnosis
Evaluation
Management
Treatment
Clinical Specialty
Anesthesiology
Critical Care
Emergency Medicine
Neurological Surgery
Nursing
Orthopedic Surgery
Pediatrics
Radiology
Thoracic Surgery
Intended Users
Advanced Practice Nurses
Emergency Medical Technicians/Paramedics
Health Care Providers
Hospitals
Nurses
Patients
Pharmacists
Physician Assistants
Physicians

# Guideline Objective(s)

• To provide guidelines on the initial assessment and management of major trauma, including airway, breathing and ventilation, circulation,

haemorrhage and temperature control

 To provide guidance on the assessment and management of major trauma, including resuscitation following major blood loss associated with trauma

# **Target Population**

Adults, young people, and children who present with a suspected major traumatic injury

Note: The following groups are not covered by this guideline: people with burns, spinal injuries, and complex fractures.

## **Interventions and Practices Considered**

- 1. Immediate destination after injury
  - Transfer to major trauma centre
  - Intermediate care in a trauma unit
- 2. Airway management in pre-hospital and hospital settings
  - Drug-assisted rapid sequence induction (RSI) of anaesthesia and intubation as the definitive method of securing the airway
  - Basic airway manoeuvres and adjuncts and/or a supraglottic device
- 3. Management of chest trauma in pre-hospital settings
  - Clinical assessment to diagnose pneumothorax
  - eFAST (extended focused assessment with sonography for trauma) to augment clinical assessment
  - Chest decompression
  - Open thoracostomy
  - Covering open pneumothorax with occlusive dressing
  - Observing for development of a tension pneumothorax
- 4. Management of chest trauma in hospital settings
  - Chest decompression of tension pneumothorax
  - Imaging to assess chest trauma (chest x-ray, eFAST, computed tomography [CT], ultrasound)
- 5. Management of haemorrhage in pre-hospital and hospital settings
  - Dressings and tourniquets
  - Pelvic binders
  - Haemostatic agents (intravenous tranexamic acid)
  - Anticoagulant reversal in hospital settings (prothrombin complex concentrate, haematologist consult)
  - Activating major haemorrhage protocols in hospital settings
  - Circulatory access in pre-hospital and hospital settings
  - Volume resuscitation in pre-hospital and hospital settings
  - Fluid replacement in pre-hospital and hospital settings
  - Haemorrhage protocols in hospital settings
  - Haemorrhage imaging in hospital settings (chest and pelvis x-rays, focused assessment with sonography for trauma [FAST], CT)
  - Whole-body CT of multiple injuries
  - Damage control surgery
  - Interventional radiology
- 6. Minimising ongoing heat loss in patients with major trauma
- 7. Pain management in pre-hospital and hospital settings
  - Pain assessment
  - Pain relief (intravenous morphine, intranasal diamorphine or ketamine)
- 8. Documentation in pre-hospital and hospital settings
  - · Recording information in pre-hospital and hospital settings
  - Receiving information in hospital settings
  - Sharing information in hospital settings
- 9. Information and support for patients, family members and carers
  - Providing support to patients, family members and carers
  - Providing support for children and vulnerable adults

- Providing information to patients, family members and carers about their injuries and management plan
- Providing information about transfer from an emergency department

#### 10. Training and skills

- Ensuring that healthcare professionals within the trauma service have the training and skills to deliver, safely and effectively, the required interventions
- Enabling healthcare professionals who delivers care to patients with trauma to have up-to-date training in the required interventions
- Providing education and training courses for healthcare professionals who deliver care to children with major trauma

## Major Outcomes Considered

- Adverse effects associated with assessment and management
- Functional scales that quantify level of disability
- Health-related quality of life
- Return to normal activities
- Healthcare contacts: duration and continuity
- Morbidity
- Mortality
- Patient-reported outcomes
- Time to operating theatre (surrogate outcome)
- Time to definitive control of haemorrhage
- Cost-effectiveness

# Methodology

## Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

# Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Clinical Guideline Centre (NCGC) on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance and related appendices.

#### Developing the Review Questions and Outcomes

Review questions were developed in a PICO framework (patient, intervention, comparison and outcome) for intervention reviews. Review questions were developed with a framework of population, prognostic factor and outcomes for prognostic reviews, and with a framework of population, index tests, reference standard and target condition for reviews of diagnostic test accuracy. This was to guide the literature searching process, critical appraisal and synthesis of evidence, and to facilitate the development of recommendations by the Guideline Development Group (GDG). They were drafted by the NCGC technical team and refined and validated by the GDG. The questions were based on the key clinical areas identified in the scope (see Appendix A).

A total of 31 review questions were identified.

Full literature searches, critical appraisals and evidence reviews were completed for all the specified review questions.

## Searching for Evidence

Clinical Literature Search

The aim of the literature search was to systematically identify all published clinical evidence relevant to the review questions. Searches were undertaken according to the parameters stipulated within the NICE Guidelines Manual (see the "Availability of Companion Documents" field). Databases were searched using medical subject headings and free-text terms. Foreign language studies were not reviewed and, where possible, searches were restricted to articles published in the English language. All searches were conducted in MEDLINE, EMBASE, and the Cochrane Library, and were updated for the final time between 18th March and 26th April 2015. No papers added to the databases after this date were considered.

Search strategies were quality assured by cross-checking reference lists of highly relevant papers, analysing search strategies in other systematic reviews, and asking GDG members to highlight any additional studies. The questions, the study types applied, the databases searched and the years covered can be found in Appendix F.

The titles and abstracts of records retrieved by the searches were sifted for relevance, with potentially significant publications obtained in full text. These were then assessed against the inclusion criteria.

#### Health Economic Literature Search

Systematic searches were undertaken to identify relevant health economic evidence within the published literature. The National Health Service Economic Evaluation Database (NHS EED), the Health Economic Evaluations Database (HEED) and Health Technology Assessment (HTA) database were searched using broad population terms and no date restrictions. A search was also run in MEDLINE and EMBASE using a specific economic filter with population terms. Where possible, searches were restricted to articles published in the English language. Economics search strategies are included in Appendix F. All searches were updated for the final time between 18th March and 26th April 2015 except in HEED which ceased production in 2014. No papers added to the databases after this date were considered.

#### Evidence Gathering and Analysis

The tasks of the research fellow are listed below and described in further detail in the full version of the guideline. The research fellow:

- Identified potentially relevant studies for each review question from the relevant search results by reviewing titles and abstracts, and deciding
  which should be ordered as full papers. Full papers were then obtained.
- Reviewed full papers against pre-specified inclusion/exclusion criteria to identify studies that addressed the review question in the appropriate population and reported on outcomes of interest (see Appendix C for review protocols)

#### Inclusion and Exclusion Criteria

The inclusion and exclusion of studies was based on the criteria defined in the review protocols (see Appendix C). Excluded studies by review question (with the reasons for their exclusion) are listed in Appendix J. The GDG was consulted about any uncertainty regarding inclusion or exclusion.

The key population inclusion criterion was:

• People of all ages with suspected major trauma

The key population exclusion criterion was:

- People with burns
- People with spinal injuries (this is covered in the NGC summary of the NICE guideline Spinal injury: assessment and initial management)
- People with complex fractures (this is covered in the NGC summary of the NICE guideline Fractures (complex): assessment and management)

Conference abstracts were not automatically excluded from any review. No relevant conference abstracts were identified for this guideline. Literature reviews, posters, letters, editorials, comment articles, unpublished studies and studies not in English were excluded.

#### Type of Studies

Randomised trials, non-randomised trials, and observational studies (including diagnostic or prognostic studies) were included in the evidence reviews as appropriate.

For most intervention reviews in this guideline, parallel randomised controlled trials (RCTs) were included because they are considered the most robust type of study design that could produce an unbiased estimate of the intervention effects. Crossover RCTs were not appropriate for any of the questions. If non-randomised studies were appropriate for inclusion, that is, non-drug trials with no randomised evidence, the GDG identified a

priori in the protocol the variables which must either be equivalent at baseline or that the analysis had to adjust for any baseline differences. If the study did not fulfil either criterion it was excluded. Please refer to Appendix C for full details on the study design of studies selected for each review question.

For diagnostic reviews, diagnostic RCTs, cross-sectional and retrospective studies were included. For prognostic reviews, prospective and retrospective cohort studies were included. Case—control studies were not included.

Where data from observational studies were included the results for each outcome were presented separately for each study and meta-analysis was not conducted.

#### Evidence of Cost-effectiveness

Evidence on cost-effectiveness related to the key clinical issues being addressed in the guideline was sought. The health economist:

- Undertook a systematic review of the economic literature
- Undertook new cost-effectiveness analysis in priority areas

#### Literature Review

#### The health economist:

- Identified potentially relevant studies for each review question from the economic search results by reviewing titles and abstracts full papers were then obtained
- Reviewed full papers against pre-specified inclusion/exclusion criteria to identify relevant studies (see below for details)

#### Inclusion and Exclusion

Full economic evaluations (studies comparing costs and health consequences of alternative courses of action: cost—utility, cost-effectiveness, cost-benefit and cost-consequence analyses) and comparative costing studies that addressed the review question in the relevant population were considered potentially applicable as economic evidence.

Studies that only reported cost per hospital (not per patient) or only reported average cost effectiveness without disaggregated costs and effects were excluded. Abstracts, posters, reviews, letters and editorials, foreign language publications and unpublished studies were excluded. Studies judged to have an applicability rating of 'not applicable' were excluded (this included studies that took the perspective of a non-Organisation for Economic Co-operation and Development [OECD] country).

Remaining studies were prioritised for inclusion based on their relative applicability to the development of this guideline and the study limitations. For example, if a high quality, directly applicable UK analysis was available other less relevant studies may not have been included. Where exclusions occurred on this basis, this is noted in the relevant section.

For more details about the assessment of applicability and methodological quality see the economic evaluation checklist (The Guidelines Manual 2012, Appendix H) and the health economics research protocol in Appendix C.

When no relevant economic analysis was found from the economic literature review, relevant UK NHS unit costs related to the compared interventions were presented to the GDG to inform the possible economic implication of the recommendation being made.

## Number of Source Documents

See Appendix D: Clinical Article Selection and Appendix E: Economic Article Selection (see the "Availability of Companion Documents" field) for detailed flow charts on the article selection process, including total number of records identified through database searching, records screened, records excluded, full-text articles assessed for eligibility, studies included in review, and studies excluded from review.

# Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

# Rating Scheme for the Strength of the Evidence

## Overall Quality of Outcome Evidence in Grading of Recommendations Assessment, Development and Evaluation (GRADE)

Level	Description	
High	Further research is very unlikely to change confidence in the estimate of effect.	
Moderate	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.	
Low	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.	
Very Low	Any estimate of effect is very uncertain.	

# Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

# Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Clinical Guideline Centre (NCGC) on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance and related appendices.

## Evidence Gathering and Analysis

The tasks of the research fellow are listed below and described in further detail in the full version of the guideline. The research fellow:

- Critically appraised relevant studies using the appropriate study design checklists as specified in The Guidelines Manual (NICE [2012] [see the "Availability of Companion Documents" field]).
- Critically appraised relevant studies with a qualitative study design NCGC checklist (see Appendix R).
- Extracted key information about interventional study methods and results using Evibase, NCGC purpose-built software. Evibase produces summary evidence tables, with critical appraisal ratings. Key information about non-interventional study methods and results were manually extracted onto standard evidence tables and critically appraised separately (see Appendix G for the evidence tables).
- Generated summaries of the evidence by outcome. Outcome data is combined, analysed and reported according to study design:
  - Randomised data is meta-analysed where appropriate and reported in Grading of Recommendations Assessment, Development and Evaluation (GRADE) profiles.
  - Observational data is presented as a range of values in GRADE profiles.
  - Diagnostic data is meta-analysed if appropriate or presented as a range of values in adapted GRADE profiles.
  - Prognostic data is meta-analysed where appropriate and reported in GRADE profiles.
  - Qualitative data is summarised across studies where appropriate and reported in themes.
- A sample of a minimum of 20% of the abstract lists of the first three sifts by new reviewers were double sifted by a senior research fellow.
   As no papers were missed by any reviewers, no further double sifting was carried out. All of the evidence reviews were quality assured by a senior research fellow. This included checking:
  - Papers were included or excluded appropriately
  - A sample of the data extractions
  - Correct methods were used to synthesis data
  - A sample of the risk of bias assessments

## Methods of Combining Evidence

Where possible, meta-analyses were conducted to combine the data from the studies for each of the outcomes in the review question using RevMan5 software.

All analyses were stratified for age (under 18 years and 18 years or over), which meant that different studies with predominant age-groups in different age strata were not combined and analysed together. For some questions additional stratification was used, and this is documented in the individual question protocols (see Appendix C). If additional strata were used this led to sub-strata (for example, 2 stratification criteria would lead to 4 sub-strata categories, or 3 stratification criteria would lead to 9 sub-strata categories) which would be analysed separately.

Analysis of Different Types of Data

See Section 4.3.3.1 of the full version of the guideline for details regarding analysis of different types of data including dichotomous outcomes, continuous outcomes, generic inverse variance, heterogeneity, and complex analysis/further analysis.

Data Synthesis for Diagnostic Test Accuracy Reviews

Two separate review protocols were produced to reflect the two different diagnostic study designs:

## Diagnostic Randomised Controlled Trials (RCTs)

Diagnostic RCTs (sometimes referred to as test and treat trials) are a randomised comparison of two diagnostic tests, with study outcomes being clinically important consequences of diagnostic accuracy (patient outcomes similar to those in intervention trials, such as mortality). Patients are randomised to receive test A or test B, followed by identical therapeutic interventions based on the results of the test (that is, someone with a positive result would receive the same treatment regardless of whether they were diagnosed by test A or test B). Downstream patient outcomes are then compared between the two groups. As treatment is the same in both arms of the trial, any differences in patient outcomes will reflect the accuracy of the tests in correctly establishing who does and does not have the condition. Diagnostic RCTs were searched for first in preference to diagnostic accuracy studies (see below). Data were synthesised using the same methods for intervention reviews (see Section 4.3.3.1 in the full version of the guideline).

#### Diagnostic Accuracy Studies

For diagnostic test accuracy studies, a positive result on the index test was found in two different ways, according to whether the index test was measured on a continuous scale or was bivariate.

For continuous index test measures, a positive result on the index test was found if the patient had values of the chosen measured quantity above or below a threshold value, and different thresholds could be used. The threshold of a diagnostic test is defined as the value at which the test can best differentiate between those with and without the target condition and, in practice, it varies amongst studies. Diagnostic test accuracy measures used in the analysis were sensitivity and specificity, and, if different diagnostic thresholds were used within a single study, area under the receiver operating characteristics (ROC) curve.

For bivariate index test measures, a positive result on the index test was found if a particular clinical sign was detected. For example, a positive test would be recorded if a fracture was observed. Diagnostic test accuracy measures used in the analysis were sensitivity and specificity.

Coupled forest plots of sensitivity and specificity with their 95% confidence intervals (CIs) across studies (at various thresholds) were produced for each test, using RevMan5. In order to do this, 2x2 tables (the number of true positives, false positives, true negatives and false negatives) were directly taken from the study if given, or else were derived from raw data or calculated from the set of test accuracy statistics.

Diagnostic meta-analysis was conducted where appropriate; that is, when 5 or more studies were available per threshold. Test accuracy for the studies was pooled using the bivariate method modelled in Winbugs®. The bivariate method uses logistic regression on the true positives, true negatives, false positives and false negatives reported in the studies. Overall sensitivity and specificity and confidence regions were plotted (using methods outlined by Novielli et al. 2010). For scores with less than five studies, median sensitivity and the paired specificity were reported where possible. If an even number of studies were reported the lowest value of the two middle pairs was reported.

Heterogeneity or inconsistency amongst studies was visually inspected in the forest plots.

## Data Synthesis for Risk Prediction Rules

Evidence reviews on risk prediction rules/tools results were presented separately for discrimination and calibration. The discrimination data was analysed according to the principles outlined under the section on data synthesis for diagnostic accuracy studies. Calibration data, e.g.,  $R^2$ , if reported, was presented separately to the discrimination data. The results were presented for each study separately along with the quality rating for the study. Inconsistency and imprecision were not assessed.

#### Data Synthesis for Qualitative Reviews

For each included paper sub-themes were identified and linked to a generic theme. An example of a sub-theme identified by patients and carers is 'keeping an open channel of communication about reasons for any delays in the emergency room' and this is linked to a broader generic theme of 'information'. In some cases, sub-themes would relate to more than one generic theme. A summary evidence table of generic themes and underpinning subthemes was then produced alongside the quality of the evidence.

Appraising the Quality of Evidence by Outcomes

Interventional Studies

The evidence for outcomes from the included RCT and observational studies were evaluated and presented using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group

The software (GRADEpro) developed by the GRADE working group was used to assess the quality of each outcome, taking into account individual study quality and the meta-analysis results.

Each outcome was first examined for each of the quality elements listed and defined in Table 2 in the full version of the guideline.

Details of how the four main quality elements (risk of bias, indirectness, inconsistency and imprecision) were appraised for each outcome are given in the full version of the guideline. Publication or other bias was only taken into consideration in the quality assessment if it was apparent.

## Overall Grading of the Quality of Clinical Evidence

Once an outcome had been appraised for the main quality elements, as above, an overall quality grade was calculated for that outcome. The scores from each of the main quality elements (0, -1 or -2) were summed to give a score that could be anything from 0 (the best possible) to -8 (the worst possible). However scores were capped at -3. This final score was then applied to the starting grade that had originally been applied to the outcome by default, based on study design. For example, all RCTs started as High and the overall quality became Moderate, Low or Very low if the overall score was -1, -2 or -3 points, respectively. The significance of these overall ratings is explained in the "Rating Scheme for the Strength of the Evidence" field. The reasons or criteria used for downgrading were specified in the footnotes of the GRADE tables.

On the other hand, observational interventional studies started at Low, and so a score of -1 would be enough to take the grade to the lowest level of Very low. Observational studies could, however, be upgraded if there was: a large magnitude of effect, a dose-response gradient, and if all plausible confounding would reduce a demonstrated effect.

See Section 4.3.5.2 to 4.3.5.4 and Tables 5 and 6 in the full version of the guideline for additional details on grading of quality of evidence for prognostic and diagnostic studies and for qualitative reviews.

#### Assessing Clinical Importance

The Guideline Development Group (GDG) assessed the evidence by outcome in order to determine if there was, or potentially was, a clinically important benefit, a clinically important harm or no clinically important difference between interventions. To facilitate this, binary outcomes were converted into absolute risk differences (ARDs) using GRADEpro software: the median control group risk across studies was used to calculate the ARD and its 95% CI from the pooled risk ratio.

The assessment of clinical benefit, harm, or no benefit or harm was based on the point estimate of absolute effect for intervention studies which was standardised across the reviews. The GDG considered for most of the outcomes in the intervention reviews that if at least 100 participants per 1000 (10%) achieved (if positive) the outcome of interest in the intervention group compared with the comparison group then this intervention would be considered beneficial. The same point estimate but in the opposite direction would apply if the outcome was negative. For the critical outcomes of mortality, any reduction represented a clinical benefit. For adverse events, 50 events or more represented clinical harm. For continuous outcomes, if the mean difference was greater than the minimally important difference then this presented a clinical benefit or harm. For outcomes such as mortality any reduction or increase was considered to be clinically important.

This assessment was carried out by the GDG for each critical outcome, and an evidence summary table was produced to compile the GDG's assessments of clinical importance per outcome, alongside the evidence quality and the uncertainty in the effect estimate (imprecision).

#### Clinical Evidence Statements

Clinical evidence statements are summary statements that are presented after the GRADE profiles, summarising the key features of the clinical effectiveness evidence presented. The wording of the evidence statements reflects the certainty/uncertainty in the estimate of effect. The evidence statements were presented by outcome and encompassed the following key features of the evidence:

- The number of studies and the number of participants for a particular outcome
- An indication of the direction of clinical importance (if one treatment is beneficial or harmful compared with the other or whether there is no difference between the two tested treatments)
- A description of the overall quality of evidence (GRADE overall quality)

#### Evidence of Cost-effectiveness

Evidence on cost-effectiveness related to the key clinical issues being addressed in the guideline was sought. The health economist:

- Undertook a systematic review of the economic literature
- Undertook new cost-effectiveness analysis in priority areas

#### Literature Review

#### The health economist:

- Critically appraised relevant studies using the economic evaluations checklist as specified in The Guidelines Manual
- Extracted key information about the study's methods and results into evidence tables (See Appendix H. Studies considered eligible but were excluded can be found in Appendix L)
- Generated summaries of the evidence in NICE economic evidence profiles (included in the relevant chapter write-ups) see below for details

#### NICE Economic Evidence Profiles

The NICE economic evidence profile has been used to summarise cost and cost-effectiveness estimates. The economic evidence profile shows, for each economic study, an assessment of applicability and methodological quality, with footnotes indicating the reasons for the assessment.

These assessments were made by the health economist using the economic evaluation checklist from The Guidelines Manual, Appendix H. It also shows incremental costs, incremental outcomes (for example, quality-adjusted life-years [QALYs]) and the incremental cost-effectiveness ratio from the primary analysis, as well as information about the assessment of uncertainty in the analysis. See Table 7 in the full version of the guideline for more details.

If a non-UK study was included in the profile, the results were converted into pounds sterling using the appropriate purchasing power parity

#### Undertaking New Health Economic Analysis

As well as reviewing the published economic literature for each review question new economic analysis was attempted by the health economist in priority areas. Priority areas for the new health economic analysis were agreed by the GDG after formation of the review questions and consideration of the available health economic evidence.

Additional data for the analysis was explored through the use of audit data and discussion with the GDG. Model structure, inputs and assumptions were explained to and agreed by the GDG members during meetings, and they commented on subsequent revisions.

One method that was used to try and link together the questions in this guideline, which are inter-related and have complex interactions (particularly around haemorrhage control), was conceptual mapping. This is an activity that involves diagrammatically representing the relationships between different areas and the interactions between interventions and outcomes, and was suggested as a softer approach of looking at the effect of different interventions and interactions between interventions on outcomes, rather than economic modelling in its more traditional form of cost utility. An example of this method is shown in Figure 4 of the full version of the guideline.

See Appendix M for details of the health economic analysis performed for the guideline.

#### Cost-effectiveness Criteria

NICE's report 'Social value judgements: principles for the development of NICE guidance' sets out the principles that GDGs should consider when judging whether an intervention offers good value for money.

In general, an intervention was considered to be cost effective if either of the following criteria applied (given that the estimate was considered plausible):

a. The intervention dominated other relevant strategies (that is, it was both less costly in terms of resource use and more clinically effective

compared with all the other relevant alternative strategies), or

b. The intervention cost less than £20,000 per QALY gained compared with the next best strategy

If the GDG recommended an intervention that was estimated to cost more than £20,000 per QALY gained, or did not recommend one that was estimated to cost less than £20,000 per QALY gained, the reasons for this decision are discussed explicitly in the 'from evidence to recommendations' section of the relevant chapter with reference to issues regarding the plausibility of the estimate or to the factors set out in the 'Social value judgements: principles for the development of NICE guidance'.

In the Absence of Economic Evidence

When no relevant published studies were found, and a new analysis was not prioritised, the GDG made a qualitative judgement about cost effectiveness by considering expected differences in resource use between options and relevant United Kingdom (UK) National Health Service (NHS) unit costs, alongside the results of the clinical review of effectiveness evidence.

The UK NHS costs reported in the guideline are those that were presented to the GDG and were correct at the time recommendations were drafted. They may have changed subsequently before the time of publication.

## Methods Used to Formulate the Recommendations

**Expert Consensus** 

## Description of Methods Used to Formulate the Recommendations

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Clinical Guideline Centre (NCGC) on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance and related appendices.

#### Who Developed the Trauma Guidelines?

The four clinical guidelines and service delivery guidance consist of related topics with overlap in populations and key clinical areas for review. The guidelines have been developed together to avoid overlap and ensure consistency. This required careful planning to ensure the Guideline Development Groups (GDGs) had the support they needed. Senior clinical expertise was recruited in addition to the standard GDG.

## Project Executive Team

The overlap in the content of the four clinical guidelines and the service delivery guidance required an approach that ensured coherence and avoided duplication across the guidelines. To address this, clinical experts from across the guidelines were recruited to form an umbrella group, the Project Executive Team (PET). The PET met quarterly throughout the development of the guidelines. At the PET meetings, the members provided expert advice to the technical team and GDGs on the crossover of reviews across guidelines.

#### Guideline Development Group Expert Members

Expert members were healthcare professionals who worked across the four clinical guidelines and the service delivery guidance, and attended the GDGs that were relevant to their expertise. The expert members provided an additional level of coherence across the guidelines, helping to identify potential duplication in the areas of their expertise.

#### Guideline Development Group (GDG)

Each guideline 'stands alone' and addresses a specific area of care. A dedicated, multidisciplinary GDG, comprising health professionals, researchers and lay members developed this guidance.

The GDG was convened by the NCGC in accordance with guidance from NICE. The GDG met for two days every 6 weeks during the development of the guideline.

Staff from the NCGC provided methodological support and guidance for the development process. The technical team working on the guideline included a project manager, systematic reviewers, health economists and information scientists. The team undertook systematic searches of the literature, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate, and drafted the guideline in collaboration with the GDG.

#### <u>Developing Recommendations</u>

Over the course of the guideline development process, the GDG was presented with:

- Evidence tables of the clinical and economic evidence reviewed from the literature. All evidence tables are in Appendix G.
- Summary of clinical and economic evidence and quality as presented in Chapters 6-17 of the full version of the guideline
- Forest plots and summary receiver operating characteristics (ROC) curves (see Appendix J)
- A description of the methods and results of the cost-effectiveness analysis undertaken for the guideline (see Appendix M)

Recommendations were drafted on the basis of the GDG interpretation of the available evidence, taking into account the balance of benefits, harms and costs. When clinical and economic evidence was of poor quality, conflicting or absent, the GDG drafted recommendations based on their expert opinion. The considerations for making consensus-based recommendations include the balance between potential harms and benefits, economic or implications compared with the benefits, current practices, recommendations made in other relevant guidelines, patient preferences and equality issues. The consensus recommendations were done through discussions in the GDG. The GDG also considered whether the uncertainty was sufficient to justify delaying making a recommendation to await further research, taking into account the potential harm of failing to make a clear recommendation.

The main considerations specific to each recommendation are outlined in the Evidence to Recommendation Section preceding the recommendation section in the full version of the guideline.

## Rating Scheme for the Strength of the Recommendations

## Strength of Recommendations

Some recommendations can be made with more certainty than others. The Guideline Committee makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the Guideline Committee is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

Interventions That Must (or Must Not) Be Used

The Guideline Committee usually uses 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally the Guideline Committee uses 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

Interventions That Should (or Should Not) Be Used – a 'Strong' Recommendation

The Guideline Committee uses 'offer' (and similar words such as 'refer' or 'advise') when confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. The Guideline Committee uses similar forms of words (for example, 'Do not offer...') when confident that an intervention will not be of benefit for most patients.

Interventions That Could Be Used

The Guideline Committee uses 'consider' when confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

# Cost Analysis

Economic evidence is provided for each review question in the full version of the guideline (see the "Availability of Companion Documents" field).

See also the "Availability of Companion Documents" field for the following:

- Appendix M: Exploration of Modelling the Time of Imaging in Major Trauma (see overview below)
- Appendix P: Additional Cost Effectiveness Considerations and Costing Detail

#### Model Overview

The aim of the economic model is to identify the most cost-effective imaging strategy and whether early imaging is cost effective in a population of suspected haemorrhage. The model involves comparing various imaging modalities (and sequences) broken down further by timing increments. The outcomes being assessed are mortality, time to discharge from hospital, and time to discharge from the intensive care unit (ICU).

The data informing the effect of the timing of imaging on outcomes is derived from the Trauma Audit Research Network (TARN) audit database, using regression as a primary method, with the results being compared to propensity score matching as a secondary method of audit data analysis. The output of the regression is in the form of predicted time of event.

There were two clinical questions in the guideline that a model on timing of imaging could help answer:

- 1. What is the clinical and cost-effectiveness of whole body computed tomography (CT) imaging in major trauma compared to selective CT imaging?
  - Timing is an implicit aspect of this question, as theoretically full body CT could be undertaken immediately with primary assessments being done whilst the patient is in the scanner, whereas comparators such as selective imaging would involve a primary assessment prior to imaging to decide which areas are most likely to be injured. An assumption made from this was that whole body CT imaging would in turn lead to some health benefits from earlier treatment, and the impact that early treatment has dictates when imaging needs to occur. In other words, imaging acts as an enabler to treatment.
- 2. What are the most clinically and cost-effective imaging strategies for detecting life threatening internal haemorrhage in major trauma patients? The model looks at a variety of imaging modalities and sequences of imaging (as well as timing). Therefore the model aims to identify the optimal time of imaging but also to define what that imaging might be. Thus implicitly capturing the trade-off between time and accuracy, as the more definitive modalities (CT) take longer than the less accurate modalities, which is an important trade-off in a time critical situation where the patient is bleeding.

## Method of Guideline Validation

External Peer Review

Internal Peer Review

# Description of Method of Guideline Validation

## Validation Process

The guidance is subject to an eight week public consultation and feedback as part of the quality assurance and peer review the document. All comments received from registered stakeholders are responded to in turn and posted on the National Institute for Health and Care Excellence (NICE) Web site when the pre-publication check of the full guideline occurs.

# **Evidence Supporting the Recommendations**

# Type of Evidence Supporting the Recommendations

Refer to the "Type of Studies" section in the "Description of Methods Used to Collect/Select the Evidence" field for a description of the studies that support the recommendations.

# Benefits/Harms of Implementing the Guideline Recommendations

## Potential Benefits

These guidelines represent the best current evidence available to support the trauma practitioner to optimally manage trauma patients. By

encouraging uniformity of care, both mortality and morbidity will fall further.

See the "Trade-off between clinical benefits and harms" sections in the full version of the guideline (see the "Availability of Companion Documents" field) for benefits of specific interventions.

## **Potential Harms**

- It is hard to make a definite diagnosis in the pre-hospital setting, so the likelihood of causing harm by carrying out an unnecessary procedure is potentially high. But where there is a life threatening tension pneumothorax intervention is required immediately. To reduce the number of unnecessary decompressions, the Guideline Development Group (GDG) limited the recommendation to intervene to people who are haemodynamically unstable or have severe respiratory compromise. The GDG agreed that people who have signs of a tension pneumothorax but are haemodynamically normal can wait until hospital for a more definitive diagnosis and possible decompression.
- Conducting an eFAST (extended focused assessment with sonography for trauma) examination increases on-scene time and delays
  transportation of the patient to hospital. In addition, the pre-hospital environment (for example, poor lighting conditions) makes it difficult to
  conduct the eFAST examination.
- In children, the GDG highlighted the radiation risks associated with computed tomography (CT) and therefore, recommended X-ray and/or ultrasound (US) as the first-line of investigation.
- If applied incorrectly, tourniquets can result in adverse effects associated with reduced blood flow (amputation, nerve palsies and renal failure) as well as result in increased venous bleeding.
- Many people thought to have a tension pneumothorax do not turn out to have a tension pneumothorax, and decompressing in patients
  without a tension pneumothorax can lead to harm. There can be significant risk of adverse events associated with some of the interventions if
  not undertaken correctly, for example, nerve damage, tissue damage, lung injury and infection. Potential adverse events of a chest drain
  include converting an open pneumothorax to a tension pneumothorax which can be life threatening.
- It was noted that, in general, the pelvic binder used should always be proprietary and not improvised due to the risks of adverse events associated with inappropriate force used in the application of improvised 'sheet' binders.
- The GDG discussed the possibility that, because they are non-invasive and generally perceived as safe, pelvic binders may be applied unnecessarily in some patients with a low index of suspicion for a pelvic fracture as staff choose to 'err on the side of caution'. The GDG confirmed that the only function of a pelvic binder is to control bleeding. The GDG felt that the over-use of pelvic binders may not cause any harm to the individual patient, but that the National Health Service (NHS) would incur the costs of equipment, possible transfer to inappropriate locations or unnecessary investigations with no corresponding benefit in outcome.
- A post-hoc sub-group analysis suggested clinical harm if tranexamic acid is administered after three hours. The GDG noted that empiric
  administration of tranexamic acid should be avoided if the patient presented more than three hours after injury. However, patients could still
  benefit from tranexamic acid after three hours if there was diagnostic evidence of continued hyperfibrinolysis.
- The GDG identified lifetime radiation risk to be a clinical harm of whole-body CT. The GDG also noted that whole-body CT may lead to unnecessary follow-up appointments for injuries that are not clinically important. In particular, the GDG noted that a whole-body CT scan will give them a radiation dose of more than 20 millisievert. This is twice the level required to give an adult aged 40 years a 1 in 1000 chance of future cancer, as defined by the National Academy of Science's Seventh Assembly of the Committee on Biologic Effects of Ionizing Radiation. The radiation dose alone is, therefore, a valid reason to limit the amount of trauma call patients with low Injury Severity Score (ISS) scores routinely undergoing CT scans.
- Testing for coagulopathy influences decisions regarding transfusion which is costly and carries potential harm. Sensitivity is the most critical
  outcome, because poor sensitivity may result in people with coagulopathy being undiagnosed and therefore, untreated. In contrast, low
  specificity, leading to false positive diagnoses, will lead to unnecessary treatments. Though carrying a risk of unnecessary adverse events and
  higher costs, such additional treatments due to misdiagnoses are unlikely to be as much of a risk to the patient as missed diagnoses.
- Two studies considered the effect of adding intravenous ketamine to intravenous morphine and found a greater analgesic effect with
  combination therapy. There was a clinical risk of nausea with morphine while ketamine increased risk of loss of consciousness in both
  studies. A single study compared intravenous morphine with intravenous paracetamol and found morphine to be a superior analgesic.
   Morphine was also found to be a better for patient satisfaction but associated with an increased adverse effect profile.
- Caution should be taken when giving pain relief intranasally and then giving intravenously due to additive dosing effects.

See the "Trade-off between clinical benefits and harms" sections in the full version of the guideline (see the "Availability of Companion Documents" field) for additional detail on harms of specific interventions.

# Contraindications

## Contraindications

Some drugs used for intranasal administration, for example, fentanyl and diamorphine, which come in suitable concentrated forms, are not available in ambulances in all areas and the use is contraindicated in cases of facial trauma or severe head injury. Caution should also be taken when giving pain relief intranasally and then giving intravenously due to additive dosing effects.

# **Qualifying Statements**

# **Qualifying Statements**

- The recommendations in this guideline represent the view of National Institute for Health and Care Excellence (NICE), arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The application of the recommendations in this guideline is not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.
- Local commissioners and/or providers have a responsibility to enable the guideline to be applied when individual health professionals and
  their patients or service users wish to use it. They should do so in the context of local and national priorities for funding and developing
  services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity
  and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with compliance with
  those duties.

# Implementation of the Guideline

# Description of Implementation Strategy

An implementation was not provided.

# Implementation Tools

Clinical Algorithm

Foreign Language Translations

Mobile Device Resources

Patient Resources

Resources

Slide Presentation

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Getting Better

## **IOM Domain**

Effectiveness

Patient-centeredness

**Timeliness** 

# Identifying Information and Availability

# Bibliographic Source(s)

National Clinical Guideline Centre. Major trauma: assessment and initial management. London (UK): National Institute for Health and Care Excellence (NICE); 2016 Feb 17. 22 p. (NICE guideline; no. 39).

# Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2016 Feb 17

# Guideline Developer(s)

National Clinical Guideline Centre - National Government Agency [Non-U.S.]

# Source(s) of Funding

The National Clinical Guideline Centre (NCGC) was commissioned by the National Institute for Health and Care Excellence (NICE) to undertake the work on this guideline.

## Guideline Committee

Guideline Development Group (GDG)

# Composition of Group That Authored the Guideline

Guideline Development Group (GDG) Members: Karim Brohi (Chair), Director, Centre for Trauma Sciences, Barts and the London School of Medicine, Queen Mary University of London; Chris Fitzsimmons, Consultant in Paediatric Emergency Medicine, Sheffield Children's Hospital NHS Foundation Trust; Simon Hughes, Consultant Anaesthetist and Director of Major Trauma, University Hospital Southampton; Heather Jarman, Clinical Director for Major Trauma and Consultant Nurse in Emergency Care, St George's University Hospitals NHS Foundation Trust, London; Richard Lee, Head of Clinical Services, Welsh Ambulance Service NHS Trust; Simon McPherson, Consultant Vascular and Interventional Radiologist, United Leeds Teaching Hospital NHS Trust; Kevin Morris, Consultant in Paediatric Intensive Care, Birmingham Children's Hospital; James Piercy, Patient member; David Skinner, Emeritus Consultant in Emergency Medicine, Oxford; Graham Stiff, GP and BASICS Pre Hospital Emergency Physician, Newbury, Berkshire; Paul Wallman, Consultant in Emergency Medicine, Brighton and Sussex University Hospitals; Nick Welch, Patient member (until March 2015)

## Financial Disclosures/Conflicts of Interest

At the start of the guideline development process all Guideline Development Group (GDG) members declared interests including consultancies, fee-paid work, share-holdings, fellowships and support from the healthcare industry. At all subsequent GDG meetings, members declared new and arising conflicts of interest.

Members were either required to withdraw completely, or for part of the discussion, if their declared interest made it appropriate. The details of declared interests and the actions taken are shown in Appendix B (see the "Availability of Companion Documents" field).

Guideline Status	
This is the current release of the guideline.	
This guideline meets NGC's 2013 (revised) inclusion criteria.	
Guideline Availability	
Available from the National Institute for Health and Care Excellence (NICE) Web site	. Also available for download in
ePub or eBook formats from the NICE Web site	
Availability of Companion Documents	
The following are available:	
<ul> <li>Major trauma: assessment and initial management. Full guideline. London (UK): National Institute for Health Feb. 330 p. (NICE guideline; no. 39). Available from the National Institute for Health and Care Excellence.</li> <li>Major trauma: assessment and initial management. Appendices. London (UK): National Institute for Health Feb. (NICE guideline; no. 39). Available from the NICE Web site.</li> <li>Major trauma: assessment and initial management. Costing report. London (UK): National Institute for Health Feb. 13 p. Available from the NICE Web site.</li> <li>Major trauma: assessment and initial management. Baseline assessment tool. London (UK): National Institute Excellence; 2016 Feb. (NICE guideline; no. 39). Available from the NICE Web site.</li> <li>Major trauma: assessment and initial management. Slide set. London (UK): National Institute for Health at 148 p. (NICE guideline; no. 39). Available from the NICE Web site.</li> <li>The guidelines manual 2012. London (UK): National Institute for Health and Care Excellence (NICE); 20 NICE Web site.</li> </ul>	the (NICE) Web site  th and Care Excellence; 2016  that and Care Excellence; 2016  tute for Health and Care  decorated in the care in the
Patient Resources	
The following is available:	
Major trauma: assessment and initial management. Information for the public. London (UK): National Institution of the public of the publi	
Excellence; 2016 Feb. 6 p. (NICE guideline; no. 39). Available from the National Institute for Health and site Also available for download in eBook and ePub formats from the NICE W	
Also available in Welsh from the NICE Web site	CO SHC

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